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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/625,137	07/25/2000	Pramod K. Srivastava	8449-123-999	8478

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT PAPER NUMBER

1642

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/625,137	Applicant(s) SRIVASTAVA, PRAMOD K.	
	Examiner Christopher H Yaen	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 17-23, 64 and 67-112 is/are pending in the application.
- 4a) Of the above claim(s) 1-14, 17-23, 64, 67-79, 82, 85-87, 89-93 and 97-103 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 80, 81, 83, 84, 88, 94-96 and 104-111 is/are rejected.
- 7) ☒ Claim(s) 94, 104-107 and 112 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/9/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Re: Srivastava K.
Priority Date: 02 June 2000

Election/Restrictions

1. Applicant's election with traverse of group XV in the reply filed on 6/17/2004 is acknowledged. The traversal is on the ground(s) that the restriction of test compounds in claims 85-92 would not be unduly burdensome to search because the search for the base claims would include the search for the different test compounds. This is not found persuasive because the test compounds in claim 85-92 which are used in the method of base claim 80 would require different search strategies. Furthermore, the test compounds include, peptides, antibodies, and small molecules, of which are structurally distinct and would require searching in diverse databases none of which are overlapping or co-extensive. Furthermore, the antibodies used as test compounds all have different specificities to different antigens.

The requirement is still deemed proper and is therefore made FINAL.

Upon further review and reconsideration, claim 84 will be rejoined and searched with the invention of group XV.

2. Claims 15-16, 24-63, and 65-66 are canceled without prejudice or disclaimer.
3. Claims 1-14, 17-23, 64, 67-112 are pending, claims 1-14, 17-23, 64, 67-79, 85-87, 89-93, and 97-103 are withdrawn from further consideration as being drawn to a non-elected invention.
4. Claims 80-81, 83-84, 88, 94-96, 104-112 are examined on the merits.

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- a. Claim 112 is examined to the extent that the claim reads on SEQ ID No: 21 only.
 - b. Base claim 80 and its dependents are examined to the extent that the “compound” and “test compound” claimed are examined to the extent that it reads on the elected invention of small molecules only.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

6. The Information Disclosure Statement filed 7/9/2004 is acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Objections

7. Claims 94, 104-107, and 112 are objected to because of the following informalities:
- a. Claims 94, and 104-107 are objected to because the claims recite a claim in the alternative that is drawn to a non-elected invention.
 - b. Claim 112 is objected to because the claim recites sequences in the alternative, which are drawn to non-elected inventions.
- Appropriate correction is required.

Claim Rejections - 35 USC § 112, 1st paragraph

8. Claims 80-81,83-84,88,94-96, and 104-111 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case has only set forth the sequence of SEQ ID No: 7 which corresponds to full length human $\alpha 2$ macroglobulin receptor (herein $\alpha 2$ MR), and therefore the written description is not commensurate in scope with the claims which read on ligand-binding fragment of $\alpha 2$ MR. Furthermore, the written description in this case has not set forth a written description for “small molecules”

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

The claims recite a “ligand binding fragment of $\alpha 2$ MR ” and “small molecules” as part of the invention. However, there does not appear to be an adequate written description in the specification as-filed of the essential structural feature that provides

the recited function of ligand binding or any structural feature that is representative of the "small molecules" claimed. The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

Applicant does not appear to have reduced to practice the entire scope of ligand binding fragments of α 2MR nor has the applicant provided sufficient written description for "small molecule". Neither has Applicant provided a sufficient written description of any structure that may be correlated with the desired function of ligand binding fragments of α 2MR or for that matter the function of a "small molecule". The specification teaches that α 2MR fragments encompasses analogs, muteins, and derivatives of the α 2MR, however, the specification has not specifically taught such fragments, analogs, muteins, or derivatives, aside from the actual α 2MR sequence (see page 38, lines 4-6, in particular). In addition, the specification defines "small molecules" as any naturally occurring, or synthetic compounds (see page 27, lines 15-20 for example), but fails to specifically teach or provide any exemplification of which

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molecules or compounds are encompassed by this term. Further, the specification fails to provided any structural or functional characteristics associated with the term "small molecule". A "ligand bind fragment of α 2MR" and "small molecule" encompass many sequences or compounds with functional activity of binding to a ligand or in the case of "small molecule" any compound which one of skill in the art constitutes as "small" (i.e. peptides, organic compounds, etc.). Thus the genus of compounds encompassed by these terms is extensive and the artisan would not be able to recognize that Applicant was in possession of the invention as now claimed.

Consequently, Applicant was not in possession of the instant claimed invention. See Regents of the University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Adequate written description of genetic material "requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id.

While it is noted that the instant claims are drawn to methods, the claims nevertheless require an adequate written description of the "ligand binding fragments of an α 2MR" and "small molecule" employed in the methods.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol.

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66, No. 4, pages 1099-1111, Friday January 5, 2001. Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 6/17/2004.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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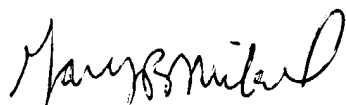
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Christopher Yaen

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September 27, 2004

A handwritten signature in black ink, appearing to read "Gary Nickol". The signature is fluid and cursive, with the first name "Gary" and last name "Nickol" clearly distinguishable.

GARY NICKOL
PRIMARY EXAMINER